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INSULIN ANALOGUES IN TYPE 1 DIABETES TREATMENT: IS THERE ACCESS AFTER BRAZILIAN UNIFIED HEALTH SYSTEM (SUS) INCORPORATION?

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Background

Type 1 diabetes mellitus (T1DM) is a chronic autoimmune disease caused by destroying the pancreatic beta cells that produce insulin. The prevalence and burden of T1DM are increasing globally. This scenario is also present in Brazil, which ranks fourth in total cases of diabetes in the world, with 4.4% of the prevalence and 4.4% of the diagnosis of T1DM in the world. Estimates show that almost 380,000 people in Brazil will have T1DM in 2022.

In T1DM, improving quality of life depends directly on glycemic control, a consequence of adequate treatment with insulin therapy. Until the beginning of the 21st century, the main human insulin used to treat T1DM was NPH insulin. During this period, poor glycemic control and episodes of nocturnal hypoglycemia were frequent with NPH. This scenario is still a reality in Brazil, where 7% of patients with T1DM have poor glycemic control. Insulin analogues emerged in the 1990s to improve glycemic control in the treatment of T1DM, due to their mechanism of action, reducing insulin peaks and presenting a more extended period of effect.

Although the advent of insulin analogues is over twenty years old, short-acting and long-acting insulin analogues were only incorporated into treating T1DM populations in Brazil in 2017 and 2019, respectively.

Their post-incorporation phase into the Brazilian Unified Health System (SUS), which includes government public purchases, is essential to analyze, not only because of the large population of patients to be treated, but also because insulin analogues are frequently the target of legal litigation in the country.

Objectives

This study analyzes the effectiveness of offering insulin analogues for treating T1DM after its incorporation into the Brazilian public health system.

Methods

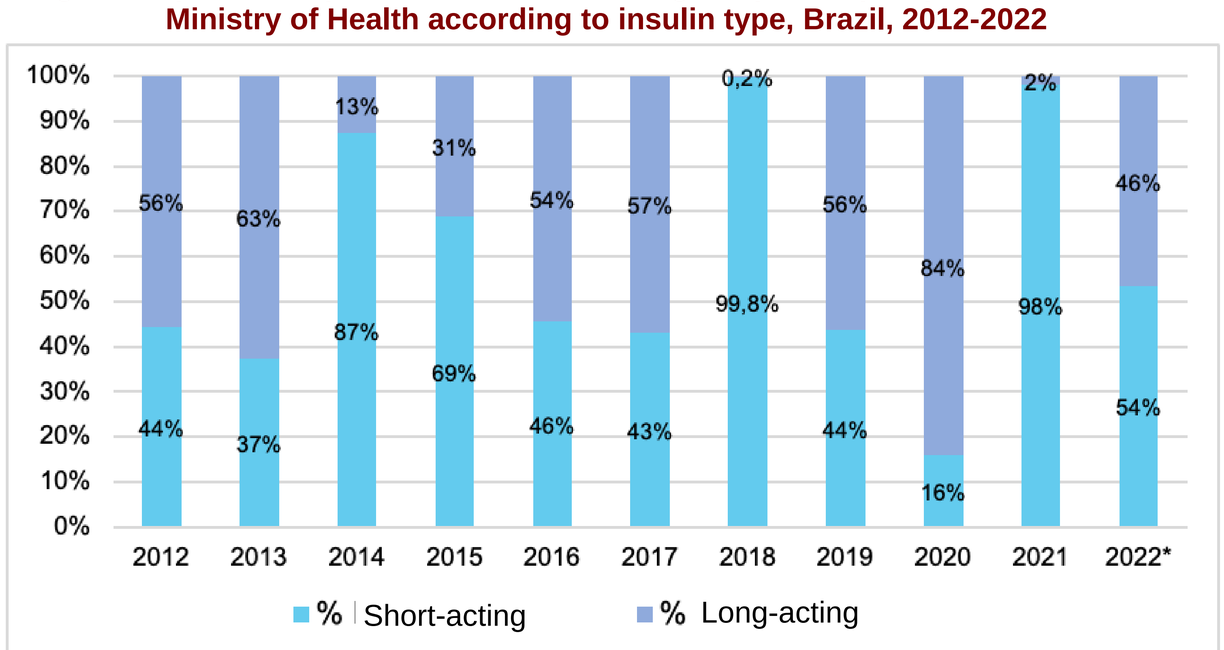
This exploratory, descriptive and retrospective research surveyed centralized purchases and dispensations of registered analogue insulins into General Services Administration's Integrated System (SIASG), integrated into Brazil's Federal Purchasing Portal and Outpatient Information System (SIA-SUS) between 2011 and 2022.

Data related to number of units purchased, unit price in BRL, total expenditure in current value in BRL, insulin dispensation after incorporation, number of units dispensed per year, total and by Brazilian state were defined as variables.

Main Results

During the period, 88,452,426 defined daily doses (DDD) of insulin analogues were acquired by the Brazilian Ministry of Health (MoH). The most significant number of insulin analogues acquired occurred in 2018 and 2021 due to the Ministry's scheduled purchases in those years. Short-acting insulin analogues were the most acquired by the MoH, totaling 85,322,715 DDDs acquired over the 11 years of analysis, representing scheduled purchases and purchases to meet legal demands. Until November 2022, 378,058 DDDs of long-acting insulin analogues were acquired, with scheduled purchases occurring only in 2013, before their incorporation into the SUS, which only occurred in 2019. Figure 1. shows the proportion of insulin analogues acquired by the Logistics Department of the MoH between 2012 and November 2022.

Fig. 1. Proportion of purchased insulin analogues (in DDD) acquired by Brazilian Ministry of Health according to insulin type, Brazil, 2012-2022



The total amount of insulin analogues acquired represented expenses of R$200,680,646.22 in values adjusted for December 2022. The acquisition of short-acting insulin analogues corresponded to 97.5% of the resources spent. Long-acting insulins represented most of the expenditure to attend lawsuits during the analyzed period. The weighted average unit prices of insulins for attended lawsuits ranged from R$2.00/DDD to R$5.46/DDD for short-acting analogues and R$3.24/DDD to R$13.90/DDD for long-acting analogues (Table 1).

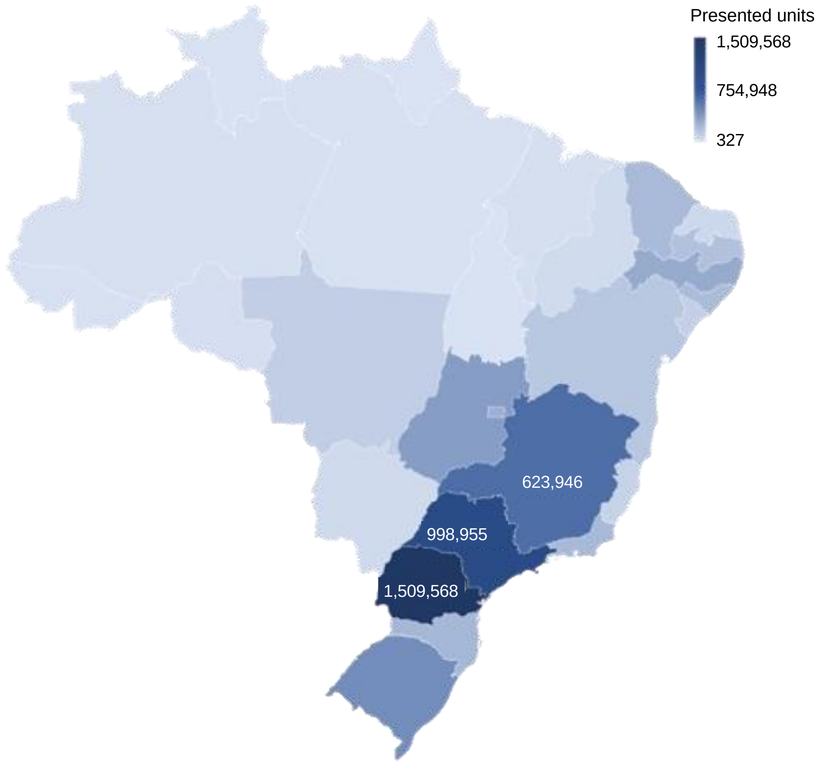
Table 1. Weighted average unit price (BRL/DDD, in current BRL) of insulin analogues to attend lawsuits, Brazil, 2012-2022

Year	Short-acting			Long-acting		
	Aspart	Glulisine	Lispro	Detemir	Degludec	Glargine
2012	BRL 2.72	BRL 2.00	BRL 2.73	BRL 5.69	-	BRL 7.97
2013	BRL 2.76	BRL 2.05	BRL 2.85	BRL 5.71	-	BRL 8.89
2014	BRL 2.84	BRL 2.06	BRL 2.80	BRL 5.79	-	BRL 8.48
2015	BRL 2.97	BRL 2.23	BRL 2.84	BRL 6.23	BRL 10.77	BRL 8.80
2016	BRL 3.25	BRL 2.46	BRL 3.15	BRL 6.91	BRL 12.11	BRL 9.81
2017	BRL 3.59	BRL 2.54	BRL 3.11	BRL 7.15	BRL 12.23	BRL 9.97
2018	BRL 3.13	BRL 2.56	BRL 3.50	BRL 7.25	BRL 12.37	BRL 6.81
2019	BRL 2.85	-	BRL 5.46	BRL 7.56	BRL 9.19	BRL 4.91
2020	-	BRL 2.35	BRL 3.27	BRL 6.75	BRL 10.80	BRL 3.24
2021	BRL 2.49	-	BRL 3.42	BRL 7.16	BRL 13.04	BRL 3.35
2022*	BRL 3.55	BRL 2.66	BRL 3.89	-	BRL 13.90	BRL 4.15

*Purchases until November 2022.

In the 11 years analyzed, only 12,498,584 units of short-acting insulin analogues were approved for dispensing by the SUS. No long-acting analogues were regularly dispensed by the SUS. The state of Paraná had the highest volume of dispensing with 1,509,568 units (12.8%) between 2018 and May 2023, surpassing São Paulo, which has the largest population in the country (998,955 units).

Fig 2. Presented pharmacotechnical units of short-acting insulin analogues to children less than four years old and pregnant women by state, Brazil, 2018-2023



Conclusions

Even though insulin analogues have been incorporated into the SUS since 2013 and the volumes of purchases and expenditures shown in this study, these insulins still present barriers to their access in the Brazilian public health system. One of the main reasons for this scenario is the lack of scheduled purchases of long-acting insulin analogues, the concentration of production in only three manufacturers, and numerous failed purchase auctions due to difficulties negotiating prices with the industries involved. It is worth noting that the use of this medication is not elective; patients with T1DM need insulin treatment to survive.

Conflict of Interest Statement

Nascimento-Costa LL states that during the beginning of this research she worked at a consulting company for the pharmaceutical industry but did not provide services related to the cited technologies. She also declares presently working for the health insurance sector in Brazil but does not have contractual relationships with any of the pharmaceutical companies that manufacture the cited technologies. Other authors have no conflicts of interest to declare.

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